

its content carefully noted. Filed concurrently herewith is a *Request for a One Month Extension of Time*, which extends the period for response to May 8, 1998. Therefore, it is respectfully submitted that this response is timely filed. Claims 1-37 are pending in the present application of which claims 1, and 15 were independent as filed.

Independent claims 1 and 15 and dependent claims 13, 16, and 28 have been rejected under §102(b) as being anticipated by U.S. Patent No. 4,289,122 to Mason et al. (hereinafter, Mason '122). Mason '122 discloses an apparatus and method of forming a foot orthosis; however, a claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference. *Verdegaal Bros. v. Union Oil Co. of California*, 1 USPQ2d 1051, 1053 (Fed. Cir. 1987). In the subject invention, the disclosure specifically states that "in order to provide additional strength and rigidity to the natural foot orthosis, a strip of heated thermoformable copolymer material is first positioned around predetermined locations on the positive mold before another heated sheet of thermoformable copolymer material is draped around the positive mold, without disturbing or moving the previously placed material." The desired effect is to combine the copolymer strip and the copolymer sheet into an integrally formed, single supporting structure. (Page 12, Lines 1-14). Mason '122, on the other hand, provides no indication that a first layer of thermoformable material is applied before a second layer to yield additional strength and rigidity. In this patent, a first layer of cooled thermoformable material

is placed next to the positive mold under a stocking. A second, heated layer of thermoformable material is then draped over the stocking, vacuum sealed and then cut. Once the second piece of material cools, the two separate pieces (greave 2 and plantar section 3) of thermoformable material are removed from the positive mold before being coupled together with the use of two rivets 10. Mason '122 clearly does not anticipate claims 1, 13, 15 and 28 of the present application as suggested by the Examiner. Favorable reconsideration is therefore requested.

The Official Action next rejects independent claim 15 and dependent claims 16, 27, and 28 as being anticipated by U.S. Patent No. 4,938,777 to Mason et al. (hereinafter, Mason '777). Mason '777 discloses a foot orthosis comprising a rigid support structure formed from a thermoplastic material wherein support is reinforced in predetermined areas with additional thermoplastic material. In this patent, the reinforcing structure or rib 10 is molded or formed integrally with the heel shell or cup 18, so that the entire rib/cup unit 11 is a unitary piece. (Column 4, Lines 33-35). The present invention, on the other hand utilizes reinforced areas that are strategically positioned depending upon the specific extremity control desired. Method claims 1 and 28 recite manipulative steps which are clearly not shown in the '777 patent. Additionally, independent claim 15 recites that the reinforcing structure is a separate strip of material integrally formed with a sheet of material. The '777 patent discloses a single design for achieving the desired reinforcement. In view of the rejection,

however, independent claim 15 and dependent claim 28 have been amended to further distinguish the present invention from the prior art. The amendment states that the reinforced areas positioned depending upon the specific extremity control desired. Applicant submits that amended claims 15 and 28 now more clearly define Applicant's claimed invention and distinguish over Mason '777 and thus are not anticipated or rendered obvious in view of Mason '777. Favorable reconsideration is therefore requested.

The Official Action also rejects dependent claims 2, 3, 17, and 18 under 35 U.S.C. §103(a) as being unpatentable over Mason '122. Here the Examiner asserts that "Mason et al. [Mason '122] does not specifically recite the composition of his thermoplastic material; however, absent a statement of criticality, the recited material would have been an obvious design choice as the selection of a known material based upon its suitability for the intended use is a design consideration within the skill of the art." To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be some reasonable expectation of success. Finally, the prior art references must teach or suggest all the claim limitations. *In re Vaeck*, 20 USPQ2d 1438 (Fed. Cir. 1991). The teaching or suggestion to make the claimed combination and the reasonable

expectation of success must both be found in the prior art, not in applicant's disclosure. *Id.*

In this case, Mason '122 recites the use of thin-sheeted polypropylene material to construct the orthosis. The present invention, however, utilizes a copolymer material having a ratio of approximately 90-10 polypropylene to polyethylene or approximately 93-7 polypropylene to polyethylene. As the Examiner has stated, Mason '122 does not recite the composition of his thermoplastic material. In fact, Mason '122 does not even disclose the use of polyethylene. Mason '122, consequently does not teach or suggest all the claim limitations. It appears that the Examiner is relying on hindsight to: (1) include polyethylene in the Mason '122 orthosis; and (2) infer a ratio of its content in comparison to the polypropylene. Under the rules of examination of the Patent Office, the mere fact that references can be combined or modified does not render the resultant combination obvious unless the prior art also suggests the desirability of the combination. MPEP §2143.01 quoting *In re Mills*, 16 USPQ2d 1430 (Fed. Cir. 1990). Mason '122 does not suggest the desirability of utilizing polyethylene in its orthosis. In fact, it teaches away from such use since it only discloses the use of polypropylene. Applicant respectfully submits that claims 2, 3, 17 and of the present invention are patentably distinguished from Mason '122. Favorable reconsideration is therefore requested.

The Official Action additionally rejects dependent claims 9 and 14 under 35 U.S.C. §103(a) as being unpatentable over Mason '122 as applied to claim 1, and further in view of U.S. Patent No. 3,916,886 to Rodgers. Here the Examiner asserts that "Mason et al. [Mason '122] discloses the instant invention as discussed, supra, but does not disclose the specifics of the reinforcing strip as claimed. Rogers discloses the desirability of a reinforced area with the approximate dimensions claimed for supporting the posterior of a foot orthosis." Again, to establish a *prima facie* case of obviousness, criteria must be met. As previously stated, Mason '122 clearly does not teach or suggest the limitations of claim 1. The Examiner mistakenly assumes that the method of constructing the orthosis of Mason '122 is similar to the method utilized in the instant invention. More specifically, the method of constructing Mason '122 does not entail the fusing together of two separate pieces of thermoformable material to accomplish a heightened degree of rigidity.

Moreover, Rodgers does not clearly show or describe the approximate dimensions of the structure claimed in the present invention. Rodgers discloses a preformed self-conforming drop foot brace that utilizes an elongate area of sufficient rigidity to maintain an upwardly extending position on a leg. Rodgers, however, does not disclose any dimensions for the elongate area. When the reference does not disclose that the drawings are to scale and is silent as to dimensions, the Examiner is not free to speculate as to these dimensions. *In re Wright* (CCPA), 193 USPQ 332.

Furthermore, the law is clear that the references must expressly or impliedly suggest the claimed invention or the Examiner must present a convincing line of reasoning as to why the artisan would have found the claimed invention to have been obvious. In the present invention, no such express or implied motivation is believed to be present and the Examiner has not provided any line of reasoning as to why it would be obvious to combine the teachings of the prior art to achieve the present invention.

Rogers also fails to specifically disclose the use of a reinforced elongate area and instead simply discloses the use of a brace wherein portions of the elongate area are thicker than other portions. More specifically, the specification in Rogers discloses that when the brace is formed, a clamp is placed over a heated sheet of polymerized resin such that when the sheet is stretched and thinned, only the side portions of the sheet are stretched and thinned while the central portion remains unstretched and in its original thickness. (Column 3, Lines 46-55).

The Official Action next rejects dependent claims 17, 18, 29, 30, and 31 under 35 U.S.C. §103(a) as being unpatentable over Mason '777 because, according to the Examiner, the recited material would have been an obvious design choice. For the reasons previously articulated with respect to Mason '122, Applicant respectfully submits that claims 17, 18, 29, 30 and 31 of the present invention are patentably distinguished from Mason '777. Favorable reconsideration is therefore requested.

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The Official Action finally rejects claim 31 as being unpatentable over Mason '177 because, according to the Examiner, "the recitation of the reinforcement being 3/16 inch is an obvious design consideration." For the reasons previously articulated with respect to Rogers, Applicant respectfully submits that claim 31 of the present invention is patentably distinguished from Rogers.

For the reasons articulated above, Applicant respectfully requests therefor that the rejection be withdrawn and favorable reconsideration be given. If any further discussion about this case would be beneficial, the Examiner is invited to contact the undersigned.

Respectfully submitted,


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